

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

*State of Montana v. Abbott Labs., Inc., et al.,*  
D. Mont. Cause No. CV-02-09-H-DWM

*State of Nevada v. American Home Products*  
*Corp., et al.,*  
D. Nev. Cause No. CV-N-02-0202-ECR

**PLAINTIFFS STATE OF NEVADA'S AND STATE OF MONTANA'S JOINT  
MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

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## I. THE STATES' CLAIMS

The Attorneys General of the States of Nevada and Montana bring these law-enforcement actions in order to enforce state laws and to protect the their Medicaid Programs and the well-being of Nevada and Montana citizens who make prescription drug payments or co-payments based on Average Wholesale Prices (“AWPs”). The scope and coverage of the Nevada and Montana Medicaid Programs are very broad. Both programs provide prescription drug coverage to “categorically needy” persons,<sup>1</sup> and Montana also covers the “medically needy”<sup>2</sup> and certain low-income families coping with serious and chronic mental illness. Nev. ¶ 125; Mont. ¶ 160.<sup>3</sup>

Both programs reimburse for all prescription drug expenditures incurred by their respective participants (minus a co-payment). Nev. ¶ 124; Mont. ¶ 159. Montana presently reimburses physicians and pharmacies at AWP less 15% for most drugs (plus a dispensing fee), and reimburses for multi-source drugs based on the Federal Upper Limit (“FUL”) set by HCFA which, in turn, is calculated based on reported AWPs. Mont. ¶¶ 162, 188. The Nevada Medicaid Program presently reimburses for outpatient drugs on the basis of AWP less 10% plus a dispensing fee. For generics for which FULs have been set, the reimbursement amount is the FUL (which, again, is calculated by reference to AWP) plus a dispensing fee. Nev. ¶¶ 126, 151.

In 2000 the Nevada Medicaid Program spent \$50,370,705 for prescription drugs, Nev. ¶ 121, while Montana spent \$60,174,213. Mont. ¶ 158. Indeed, the Montana Medicaid Program accounts for approximately 15% of all prescriptions written in the State. Mont. ¶ 161. Thus, Montana and Nevada have made reimbursements based on AWPs for all of the drugs identified

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<sup>1</sup> “Categorically needy” persons include individuals eligible for cash benefits under the Aid to Families with Dependent Children program, the aged, blind, or disabled individuals who qualify for supplemental security income benefits, and other low-income groups such as pregnant women and children entitled to poverty-related coverage. 42 U.S.C. § 1396a(a)(A)(i).

<sup>2</sup> The “medically needy” are individuals who meet the nonfinancial eligibility requirements for inclusion in one of the groups covered under Medicaid, but whose income or resources exceed the financial eligibility requirements for categorically needy eligibility. 42 U.S.C. § 1396a(a)(10)(C).

<sup>3</sup> “Mont. ¶” references paragraphs in the State of Montana’s Second Amended Complaint. “Nev. ¶” references paragraphs in the State of Nevada’s Amended Complaint.

in the State complaints; so, too, have Nevada and Montana citizens, on whose behalf the States pursue claims in *parens patriae*.

Nevada and Montana allege that defendants have engaged in a scheme to inflate AWP's for certain drugs,<sup>4</sup> which causes the States to over-reimburse for drugs covered under their Medicaid programs. Nev. §§ 1-10; Mont. §§ 1-10. The damage to the Medicaid programs is exacerbated "on the back end" when defendants underpay rebates. Pursuant to an agreement with the Center for Medicare and Medicaid Services ("CMS"), each manufacturer pays quarterly rebates directly to the States that are intended to afford Medicaid access to a manufacturer's "Best Price." For brand name drugs, the rebate equals the greater of 15.1% of Average Manufacturers' Price ("AMP") or the difference between AMP and Best Price. 12 U.S.C. § 1396r-8(c). Defendants report both AMP and Best Price each quarter. Best Price is generally defined as the lowest price at which the manufacturer sells the drug to any purchaser. Nev. §§ 383-91; Mont. §§ 603-11. In keeping with their artificial price inflation scheme, each defendant did not report the actual Best Price, but instead reported higher prices that excluded discounts and other inducements offered to physicians, such as free goods, volume discounts, rebates, educational grants and other programs that lower the providers' actual cost of the drugs. Consequently, defendants paid rebates lower than those actually due had defendants accurately reported Best Prices. Nev. § 392; Mont. § 612.

Nevada asserts six causes of action under Nevada law in order to stop and remedy defendants' unlawful conduct: (i) three separate claims for violations of the Nevada Deceptive Trade Practices Act (N.R.S. 598.0903, *et seq.*) on behalf of the State of Nevada and its residents, with the second of these claims brought to remedy deceptive trade practices directed at elderly Nevada residents (Nev. §§ 423-43); (ii) a claim for treble damages and various forms of

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<sup>4</sup> Each drug for which relief is sought is identified in the body of the State complaints and in Appendix A attached to those complaints. So, for instance, Appendix A to the Montana Second Amended Complaint identifies approximately 327 drugs by manufacturer, name, generic name (if applicable), and National Drug Code ("NDC") number. Appendix A also sets forth the fraudulent AWP's for each drug, usually over multiple years. The Nevada Amended Complaint sets forth the exact same information, but for a smaller group of defendants (Nevada is pursuing the remaining defendants in Nevada state court pursuant to the Court's remand order in *Nevada I*).



equitable relief, including civil forfeiture and restitution, under Nevada's civil RICO statute, N.R.S. 207.470, *et seq.* (Nev. §§ 444-66); (iii) a claim for cost recovery and civil penalties pursuant to Nevada's Medicaid fraud statutes found at N.R.S. 422.540, *et seq.* (Nev. §§ 467-77); and (iv) a claim for punitive damages (Nev. §§ 478-79).

Similarly, Montana brings five counts under Montana law: (i) two separate claims for deceptive trade practices in violation of the Unfair Trade Practices and Consumer Protection Act (MONT. CODE ANN. § 30-14-101, *et seq.*) on behalf of the State of Montana and its residents (Mont. §§ 654-67); (ii) a claim for cost recovery pursuant to Montana's Medicaid fraud statutes found at MONT. CODE ANN. §§ 53-6-160 and 53-6-143(4) (Mont. §§ 668-79); (iii) a claim for forfeiture, civil penalties, double damages and legal costs under Montana's false claims statute, MONT. CODE ANN. § 17-8-231 (Mont. §§ 680-91); and (iv) a claim for punitive damages (Mont. §§ 692-93).<sup>5</sup>

## II. ARGUMENT

### A. The Medicaid Rebate Statute Does Not Preempt The Best Price Claims

Defendants assert that the States' Best Price claims are impliedly preempted. Defs. Br. at 6-11. Although defendants cite the correct standard for determining whether "implied conflict preemption" applies,<sup>6</sup> they misapply that standard and overlook important precedents that take a very narrow view of preemption under the Medicaid Act.

In *Concannon*, industry trade organization Pharmaceutical Research and Manufacturers of America ("PhRMA") challenged a Maine statute that applied prior authorization requirements within the State Medicaid Program to manufacturers who failed to enter rebate agreements with

<sup>5</sup> Defendants Gensia, Inc. and Gensia Sicor have not moved to dismiss, thus the claims asserted will proceed against the defendants.

<sup>6</sup> Implied conflict preemption arises where the "state law interposes an obstacle to the achievement of Congress's discernable objectives" or where "compliance with both state and federal regulations is impossible." *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 74-75 (1st Cir. 2001) (quoting *Grant's Dairy-Me., LLC v. Commissioner of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000)), *aff'd sub nom.*, 123 S. Ct. 1855 (2003); *In re Pharm. Indus. Average Wholesale Price Litig. ("AWP")*, 263 F. Supp. 2d 172, 188 (D. Mass. 2003).

the State in connection with a separate, non-Medicaid prescription drug program. Perceiving prior authorization requirements as a competitive disadvantage,<sup>7</sup> 249 F.3d at 71-72, PhRMA contended that the Maine Act interfered with the delivery of Medicaid services and was therefore preempted by the Medicaid Act. *Id.* at 76.

The First Circuit disagreed, finding no conflict between the Maine Act and Medicaid's structure and purpose, especially since Medicaid expressly permitted prior authorization requirements generally. *Id.* Unmoved by PhRMA's assertion that the requirement imposed by Maine furthered no Medicaid purpose, the court explained that the question was whether a conflict existed with the Medicaid Act or its purposes. *Id.* Importantly, the court explained that federal preemption of state law within the jointly administered state-federal Medicaid Program is disfavored:

[W]e assume "that the historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." . . . We also recognize that federal preemption of a state law is "strong medicine," and is "not casually to be dispensed." . . . This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism": "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one."

*Id.* at 75 (citations omitted). Applying this standard, the court found "no basis for inflicting the 'strong medicine' of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program." *Id.* at 76.

In the instant case, defendants fail to identify a valid conflict with the Medicaid Act itself or its purposes. The reason for defendants' omission is obvious: the States' claims directly advance the purpose of the Medicaid Program by seeking to eradicate fraud. Medicaid is a joint state-federal program in which the States are "afforded some latitude in the way in which they

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<sup>7</sup> Part of the Rebate Statute, the prior authorization requirement, when invoked by a state, provides that a drug may not be dispensed to a Medicaid beneficiary without the prior approval of the State Medicaid administrator. *See* 42 U.S.C. § 1396r-8(d)(5).

provide Medicaid to beneficiaries within their States.” *Pharmaceutical Research & Mfrs. of Am. v. Meadows*, 184 F. Supp. 2d 1186, 1194 (N.D. Fla. 2001). The states administer the program, and the federal government reimburses the state for a portion of the costs, as long as the state plan has been approved by the federal government and otherwise abides by Medicaid Act regulations. *See* 42 U.S.C. §§ 1396a(a), (b). The Supreme Court has mandated that “State Medicaid plans must comply with requirements imposed both by the Act itself and by the Secretary of Health and Human Services.” *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981). One of those requirements is that the State maintain a Medicaid Fraud Control Unit with responsibility for, *inter alia*, “conducting a statewide program for the investigation and prosecution of violations of *all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title . . .*” 42 U.S.C. § 1396b(q)(3) (emphasis added); *see also* 42 U.S.C. § 1396a(61) (“A State plan for medical assistance *must* . . . provide that the State must demonstrate that it operates a Medicaid fraud and abuse control unit described in section 1903(q) [42 U.S.C. §1396b(q)] that effectively carries out the functions and requirements described in such section, . . .”) (emphasis added); 42 U.S.C. § 1396a(25) (state must “take all reasonable measures to ascertain the legal liability of third parties” and pursue reimbursement).

Thus, far from conflicting with the Medicaid Act, the States’ claims actually *implement* the Act’s *mandate* that the States “prosecute[] violations of all applicable State laws regarding any and all aspects of fraud in connection with [the Medicaid Act].” Furthermore, the States’ Best Price claims are consistent with the Rebate Statute’s purpose of providing cost savings directly to the States. *See, e.g., Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855, 1860 (2003). “Congress imposed the rebate requirement for two overlapping reasons: to reduce the cost of Medicaid and to prevent pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs.” *Pharmaceutical Research*

*& Mfrs. of Am. v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001). Hence, the rebates are intended to ensure that the States obtain at least the best prevailing wholesale price for drugs that they purchase for Medicaid beneficiaries, *id.* at 221, and Nevada and Montana's Best Price claims here seek to ensure that each State indeed receives the full rebates owed. As such, these claims further the purposes of the Rebate Statute. *See Walsh*, 123 S. Ct. at 1868 (Actions that states take to "[a]void[] unnecessary costs in the administration of a State's Medicaid program obviously serve[] the interests of both the Federal Government and the States that pay the cost of providing prescription drugs to Medicaid patients.").

That the Rebate Statute provides the Secretary with various powers of enforcement, as defendants point out (*see* Defs. Br. at 8-9), does not create any conflicts. If so, then every State's Medicaid Fraud Statute would be void *ab initio* for conflicting with the federal Medicaid Fraud Statute. Of course, this is not the case. Furthermore, in surveying the Secretary's enforcement powers under the Rebate Statute, defendants fail to note that the provision authorizing the Secretary to impose penalties for the submission of false Best Price information is not exclusive and contemplates the application of other laws. "Such civil money penalties are *in addition to* other penalties as may be prescribed by law." 42 U.S.C. § 1396r-8(b)(1)(A)(3)(C)(ii) (emphasis added). No provision of the Rebate Statute suggests, much less mandates, that the Secretary has the exclusive power to remedy fraud in the Rebate portion of the Medicaid Program.

None of defendants' authorities counsel otherwise. For instance, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), which was not decided under the Medicaid Act, does not apply. In rejecting claims based on misrepresentations that the defendant allegedly made to the Food and Drug Administration ("FDA") in obtaining approval to market a bone screw device, the Supreme Court found a conflict between the FDA's power to punish and deter fraud and "fraud-on-the-FDA claims under state tort law." *Id.* at 348. Plaintiffs' claims, if permitted, would upset the relevant statute's flexibility in providing the FDA with enforcement options ranging from injunctive relief and civil penalties to seizing the device, as would

compliance with 50 different state tort regimes. *Id.* at 349-50. In short, Congress expressly “intended that the [statute] be enforced exclusively by the Federal Government.” *Id.* at 352.

This Court has already rejected the application of *Buckman* in the Medicare Act context. *See AWP*, 263 F. Supp. 2d at 188-89 (noting that “the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs’ harm”). Furthermore, the concerns raised in *Buckman* do not apply here due to a critical difference between the two regulatory regimes. Far from fearing the application of numerous state laws to fraud within the Medicaid Program or intending the federal government to be the sole enforcer of Medicaid laws, Congress expressly directed the States to share in the policing function by deploying “all applicable State laws regarding any and all aspects of fraud in connection with [the Medicaid Program].” 42 U.S.C. § 1396b(q)(3).<sup>8</sup> Of course, this is only logical given that (i) the states make the prescription drug reimbursements (only a portion of which are reimbursed by the federal government), and (ii) the rebates are paid *directly* to the states. Nor do defendants face the “specter of a patchwork of liability” due to varying definitions of “Best Price” under each State’s respective Medicaid fraud statute. *See* Defs. Br. at 9. This is because the Rebate Statute itself sets forth a *single* definition of “Best Price,” *see* 42 U.S.C. § 1396r-8(c)(1)(C), which will be the benchmark for determining whether defendants have engaged in fraud in violation of Montana and Nevada statutes; therefore, diverse courts will not be divining diverse “Best Price” definitions as defendants’ *posit*. And, in any event, this Court has already recognized that “state courts frequently construe terms in federal laws in order to adjudicate causes of action based in state law, and the Supreme Court [remains] the ultimate decision-maker on federal questions arising out of state court.” *AWP*, 263 F. Supp. 2d at 188-89.

Defendants’ other cases are likewise unpersuasive here because, in each, state laws prohibiting pharmacists from collecting co-pays conflicted with a provision of the Rebate Statute

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<sup>8</sup> Indeed, the federal government funds 75 % of the operating costs of each State’s Medicaid Fraud Control Unit. 42 U.S.C. § 1396b(a)(6).

that was passed to protect the actual level of reimbursements made to pharmacists. *See* Defs. Br. at 10-11 (citing *Pharmaceutical Soc'y v. New York State Dep't of Social Servs.*, 50 F.3d 1168 (2d Cir. 1995); *Nebraska Pharmacists' Ass'n v. Nebraska Dep't of Social Servs.*, 863 F. Supp. 1037, 1043 (D. Neb. 1994); *Indiana Pharmacists Ass'n v. Indiana Family & Soc. Servs. Admin.*, 881 F. Supp. 395, 398 (S.D. Ind. 1994)).<sup>9</sup> Again and in contrast, no conflicts exist here between the States' Best Price claims and any provision of Medicaid Act, including the Rebate Statute.<sup>10</sup>

Indeed, no court has ever read the Federal Medicaid Act as preventing a State from seeking a remedy for Medicaid fraud. Rather, the authorization for states to pursue all available means under 42 U.S.C. § 1396a(a)(25)(B) "furthers the ultimate goal of Medicaid – that the program 'be the payer of last resort.'" *See, e.g., Costello v. Geiser*, 647 N.E.2d 1261, 1262 (N.Y. 1995) (quoting Sen. Rep. No. 146, 99<sup>th</sup> Cong., 2d Sess., 312, *reprinted in* 1986 U.S. Code Cong. & Admin. News 279). Defendants' bankrupt preemption argument is entirely inconsistent with the wording and purposes of the Medicaid Act and the very existence in Nevada and Montana – and in virtually *every* state – of Medicaid Fraud statutes explicitly authorizes States to prosecute and seek remedies for Medicaid fraud.

**B. The Best Price Claims Are Valid Causes Of Action Under The Medicaid Fraud Statutes**

Defendants claim that the Montana and Nevada Medicaid Fraud statutes cannot reach their misconduct because Best Prices are submitted to CMS and not to State agencies. Defs. Br. at 11-12. Defendants are wrong. Both statutes contemplate the provision of false information indirectly and, in any event, defendants pay rebates directly to the States.

N.R.S. 422.540(1) provides that "[a] *person*, with the intent to defraud, commits an offense if with respect to the plan he:

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<sup>9</sup> Furthermore, defendants failed to disclose that district courts are not in accord on this single issue. *See, e.g., Florida Pharmacy Ass'n v. Williams*, 871 F. Supp. 1441 (N.D. Fla. 1993).

<sup>10</sup> Nor will the States' Best Price claims result in substantial changes in federal Medicaid reimbursements as defendants claim. Defs. Br. at 10. The federal government does not share in any rebates, which are paid directly and solely to the States.



(a) Makes a claim or *causes it to be made*, knowing the claim to be false, in whole or in part, by commission or omission; [Emphasis added.]

(b) Makes or *causes to be made* a statement or representation for use in obtaining or seeking to obtain authorization to provide specific goods or services, knowing the statement or representation to be false, in whole or in part, by commission or omission; [Emphasis added.]

\* \* \*

(d) Makes or *causes to be made* a statement or representation for use in qualifying as a provider, knowing the statement or representation to be false, in whole or in part, by commission or omission. [Emphasis added.]

Nevada alleges that defendants have violated these sections by paying rebates based on falsely reported Best Prices. Nev. §§ 474-75.<sup>11</sup>

Defendants argue that N.R.S. 422.540(1) applies only to “providers” in the traditional sense, Defs. Br. at 11, but that is not what the statute says. Its prohibitions extend to any “person,” not to any “provider.” In any event, defendants are providers for purposes of liability for treble damages and civil penalties under N.R.S. 422.580, because they “participate[] in the plan as the provider of goods . . . .” N.R.S. 422.490(1). Defendants cannot contest that they provide drugs used in the Nevada Medicaid Program. Defendants also assert that a Best Price misrepresentation is not made “with respect to the plan,” Defs. Br. at 12, but this argument defies logic. Of course it is made “with respect to the plan” when Best Price is the basis upon which rebates *to the plan* are calculated. Defendants also take a too narrow view of what constitutes a “claim.” “Claim” is broadly defined as “a communication . . . which is used to identify specific goods . . . as reimbursable pursuant to the plan, or which states income or expense and is or may be used to determine a rate of payment pursuant to the plan.” N.R.S. 422.470. A rebate payment falls within this definition because it is both a communication used to identify specific drugs that are reimbursed by the plan and an income or expense used to determine the rate of payment

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<sup>11</sup> Nevada also alleges that defendants violated N.R.S. 422.540(1)(c) for falsely reporting AWP. See Nev. § 476. Defendants do not move to dismiss this particular claim, which is not a Best Price claim.

(because it goes into the calculation of the net cost of each drug, after rebates). And in focusing only on the definition of “claim” in the prohibition of N.R.S. 422.540(1)(a), defendants overlook the general prohibitions against submitting false statements or representations contained in N.R.S. 422.540(1)(b)-(d). The definition of “statement or representation” is even broader than “claim” and “includes, without limitation, a report, claim, certification, acknowledgment or ratification of . . . [f]inancial information.” N.R.S. 422.525(1).

Defendants’ arguments fare no better under the Montana Medicaid Fraud statute. MONT. CODE ANN. § 53-6-160(1) provides that “[a] person who submits to a medicaid agency . . . information that is or may be used to determine eligibility for medicaid benefits, . . . or the amount of payment under the medicaid program is considered to represent to the department, to the best of the person’s knowledge and belief, that the item is genuine and that its contents, including all statements, claims and representations contained in the document, are true, complete, accurate, and not misleading.” Montana alleges that defendants have violated this statute by paying rebates based on falsely reported Best Prices. Mont. ¶ 675.<sup>12</sup>

Defendants complain that the rebate amounts submitted to Montana are not used to determine the amount of a “payment” under the Medicaid Program, Defs. Br. at 12, yet that is precisely what the rebate does. The rebates, in conjunction with the reimbursement amounts, determine the net amount of reimbursements – or “payments” – for each drug.

The gravamen of defendants’ arguments against the application of both statutes is the purported indirect nature of the Best Price fraud given that defendants report Best Prices to CMS and not directly to the states. But defendants overlook the broad scope of both statutes, which apply to indirect claims and representations. In Nevada, the prohibition extends not just to a person who makes a claim or false statement, but also to persons who “*cause*[ ] [them] to be made.” N.R.S. 422.540(1)(a)-(d) (emphasis added). Likewise, the Montana statute provides that

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<sup>12</sup> Montana also alleges that defendants violated MONT. CODE ANN. § 53-6-160(1) for falsely reporting AWP’s. See Mont. ¶ 676. Defendants do not move to dismiss this particular claim, which is not a Best Price claim.



“[a] person is considered to have made or to have authorized to be made a claim, statement, or representation if the person . . . exercised . . . authority or responsibility [for making a claim, statement or representation] and, as a direct *or indirect* result, the false statement was made . . .” MONT. CODE ANN. § 53-6-160(4) (emphasis added). Thus, it is immaterial that the Best Prices were submitted to CMS and not directly to Nevada and Montana, for the claims and statements fall within the purview of the acts.<sup>13</sup> Furthermore, and perhaps more importantly, defendants submit rebate amounts directly to the States. This rebate constitutes a representation of the amount owed under the Rebate Statute. If the rebate is too small because defendants inaccurately report Best Prices, it is a claim or misrepresentation made directly to the States.<sup>14</sup>

Not surprisingly, defendants are unable to identify a single case in which a court foreclosed Nevada or Montana from recovering based upon misrepresentations – either direct or indirect – that caused each State’s Medicaid Program to overpay in violation of the Medicaid Fraud statutes.

### C. Montana States A Claim For Violation Of The False Claims Act

MONT. CODE ANN. § 17-8-231(1) establishes liability for the submission of false claims to any State agency:

A person who knowingly presents or *causes* to be presented a false, fictitious, or fraudulent claim for allowance or

<sup>13</sup> See also the False Claims Act cases cited *infra* in Section III.C. holding that claims need not be submitted directly to the State as long as there is a nexus between the information provided and the expenditure of State funds. Defendants also overlook relevant federal regulations mandating that each state plan contain provisions for identifying and pursuing “third parties liable for payment of services under the plan and for payment of claims involving third parties.” 42 C.F.R. § 433.137; see also 42 C.F.R. § 433.138 (entitled “Identifying liable third parties” and specifying: “The [state] agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan.”). “Third party” is broadly defined as “*any individual, entity or program* that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.” 42 C.F.R. § 433.136(3) (emphasis added).

<sup>14</sup> Defendants overlook the highly symbiotic relationship between the States and defendants within the Rebate Program. Each quarter the States report to the manufacturers the total number of units of each drug for which payment was made under the plan during the period, and these units are used in the calculation of rebate payments. 42 U.S.C. § 1396r-8(b)(2)(A). And, although the manufacturers report AMP and Best Price data to CMS, defendants submit rebate amounts directly to the States. Thus, the Rebate Program is not one merely administered by the federal government for the benefit of the States. Rebates are a materially important part of each State’s Medicaid Program and are used to reduce the net cost of drug reimbursements. Accordingly, misrepresentations about Best Prices and Rebates adversely impact the program and are redressable by applying Medicaid Fraud statutes.

payment to any state agency or its contractors forfeits the claim, including any portion that may be legitimate, and in addition is subject to a penalty not to exceed \$2,000 plus double the damages sustained by the state as a result of the false claim, including all legal costs. [Emphasis added.]

Montana alleges that defendants violated the Montana False Claims Act by paying rebates based on falsely reported Best Prices. Mont. ¶ 687.

In a familiar refrain, and again without citing any case authority, defendants argue that the Montana False Claims Act cannot apply because no claim was made to the “state agency or its contractors.” Defs. Br. at 12.<sup>15</sup> Although no reported decisions under the Montana False Claims Act exist, this Court has held under the analogous federal False Claims Act (31 U.S.C. § 3729-33) that it could be unlawful to encourage doctors – that is, third-parties – to bill Medicaid for off-label uses of the drug Neurontin. As the Court explained, although “a pharmaceutical manufacturer . . . did not itself submit false claims in the form of off-label prescriptions directly to the government,” defendants’ acts of inducement suffice. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51 (D. Mass. 2001); *see also id.* at 52-53 (“[T]he participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.”).

The Illinois False Claims Act was recently construed in the same manner, with the court noting that “[t]he statute does not require that the claim be submitted to the State or that the State pay the claimant directly” as long as “some nexus between the claim and the State’s funds or property” exists. *People ex rel. Levenstein v. Salafsky*, 2003 Ill. App. Lexis 560, at \*15-16 (Ill. App. Ct. May 5, 2003) (upholding claim where complaint alleged that University was partially funded by the State);<sup>16</sup> *see also United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731,

<sup>15</sup> Montana also alleges that defendants violated the False Claims Act through their misrepresentations of AWP’s, *see* MONT. CODE ANN. § 688, but defendants do not move to dismiss this part of the False Claims Act claim on this basis.

<sup>16</sup> The Illinois act at issue in *Levenstein* imposed liability on any person who knowingly made, used, or caused to be made or used a false record or statement “to get a false or fraudulent claim paid or approved by the State.” *Id.*, at \*7 (quoting 740 ILCS 175/3(a)(2)).

738 (D.C. Cir. 1998) (upholding claim where there is a “sufficiently close nexus between the [grantee and the government] such that a loss to the former is effectively a loss to the latter”).

Here, and as already noted, the rebate itself constitutes a representation of the amount owed under the Rebate Statute, and if the rebate is too small because defendants inaccurately report Best Prices, it is a claim or misrepresentation made directly to the States. Alternatively, defendants report Best Prices to CMS knowing full well that they are used to calculate rebates to the States. Hence, and as Montana alleges, misrepresenting Best Prices had the “foreseeable” and “intended consequence” of depriving Montana of full rebates owed. *See Parke-Davis*, 147 F. Supp. 2d at 52-53. Defendants simply cannot successfully argue that there is no nexus between misrepresenting Best Prices to CMS and the associated deprivation of monies owed to Montana.

Defendants also assert that no “claim” was made, citing to the definition of “claim” under the Medicaid Fraud Statute. Defs. Br. at 13 (citing MONT. CODE ANN. § 53-6-155(4)). The Montana False Claims Act does not define “claim,” but under the federal act a claim “includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(c). This Court has noted that an action may be brought where there is “(1) . . . a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money *or to forfeit moneys due* (i.e., that involved a ‘claim’).” *Parke-Davis*, 147 F. Supp. 2d at 50 (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999)) (emphasis added). Furthermore, the Court has emphasized that the act reaches beyond “claims” to all fraudulent attempts to deprive the government of monies:

***[The False Claims Act is] intended to reach all types of fraud, without qualification, that might result in financial loss to the***

**Government** . . . The Act is broadly phrased to reach any person who makes or causes to be made any claim upon or against the United States . . . The Court has consistently refused to accept a rigid, restrictive reading [of the Act] . . . ***This remedial statute reaches beyond “claims” which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.***

*Parke-Davis*, 147 F. Supp. 2d at 50-51 (emphasis added).

The Court should interpret the meaning of “claim” under Montana’s act in a likewise manner to capture defendants’ concerted scheme to deprive the State of rebate monies, as defendants’ fraudulent acts have caused Montana to “forfeit moneys due.” *Id.* at 50.

**D. Defendants’ “Government Knowledge” Contentions Provide No Basis For Dismissing The AWP Claims**

After years of reporting falsely inflated AWP’s, defendants now have the audacity to assert that the States’ deceptive trade practices claims, as well as the Nevada RICO and Montana False Claims Act counts, should be dismissed because the States knew, or should have known, all along that they were being deceived. Defs. Br. at 13-16. These assertions are unfounded, belie a serious misunderstanding of the nature of the States’ claims, and, in any event, raise factual issues to be determined later in the litigation and not on a Rule 12(b)(6) motion.

**1. Estoppel Does Not Apply to Nevada and Montana**

Defendants’ “government knowledge” contentions are thinly veiled arguments of estoppel. However, when the government brings a suit in the public interest, as the States do here, the defenses of estoppel and laches do **not** apply unless “exceptional” circumstances exist or manifest injustice would result. *See, e.g., Chennault v. Sager*, 610 P.2d 173, 176 (Mont. 1980); *Billings v. Pierce Packing Co.*, 161 P.2d 636, 640 (Mont. 1945); *Board of County Comm’rs v. C.A.G., Inc.*, 654 P.2d 531, 533 (Nev. 1982) (“Where a public right and the protection of the public are involved, the doctrine of estoppel is to be invoked only in rare and unusual circumstances, and should not apply where it would defeat a policy adopted to protect the public.”); *Santiago v. Immigration & Naturalization Serv.*, 526 F.2d 488, 491-92 (9th Cir.

1975); *United States v. Vulcanized Rubber & Plastics Co.*, 178 F. Supp 723, 726 (D. Pa. 1959), *aff'd*, 288 F.2d 257 (3d Cir. 1961).

Affirmative misconduct may constitute “exceptional” circumstances permitting application of the doctrine against a government. *See, e.g., Pierce v. Apple Valley, Inc.*, 597 F. Supp. 1480, 1488-89 (S.D. Ohio 1984). Affirmative misconduct means (i) affirmative conduct, not omissions to act, and (ii) some fraudulent concealment, misrepresentation or other bad faith conduct on the part of the government. *Id.* at 1488-89. Defendants do not argue, nor could they, that the States have engaged in any affirmative misconduct. And, in any event, whether exceptional circumstances exist is a *fact-based* inquiry depending on the circumstances of each case, *Chennault*, 610 P.2d at 176, and therefore cannot be decided on a Rule 12(b)(6) motion.

**2. Montana Need Only Plead that Defendants’ Conduct had the Tendency or Capacity to Deceive**

The Montana Unfair Trade Practices and Consumer Protection Act (“CPA”) declares that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce” are unlawful. MONT. CODE ANN. § 30-14-103. The CPA is based on the Federal Trade Commission Act (15 U.S.C. § 45(a)(1)) (the “FTCA”) and directs courts to consider FTC and federal court interpretations of the FTCA when construing the CPA. MONT. CODE ANN. § 30-14-104. In doing so, the CPA “should be liberally construed with a view to effect its object and to promote justice.” *Baird v. Norwest Bank*, 255 Mont. 317, 327, 843 P.2d 327 (1992).

Under the test for determining whether an act is unfair or deceptive, the State’s actual knowledge is irrelevant, because the proper inquiry is whether the act or practice has the capacity to deceive the “less sophisticated consumer.” *Jeter v. Credit Bureau*, 760 F.2d 1168, 1172-75 (11th Cir. 1985) (applying FTCA test to case under Federal Debt Collection Practices Act); *Charles of The Ritz Distribs. Corp. v. Federal Trade Comm’n*, 143 F.2d 676, 679 (2d Cir. 1944) (FTCA “was not ‘made for the protection of experts, but for the public – that vast multitude

which includes the ignorant, the unthinking, and the credulous.”) (quoting *Florence Mfg. Co. v. J. C. Dowd & Co.*, 178 F. 73, 75 (2d Cir. 1910)). Capacity to deceive, rather than actual deception, is the primary criterion for establishing whether a particular type of conduct amounts to misrepresentation. *See, e.g., Trans World Accounts, Inc. v. FTC*, 594 F.2d 212, 214 (9th Cir. 1979) (decided under FTC Act). Neither intent to deceive nor actual deception is required. *Dwyer v. J.I. Kislak Mortgage Corp.*, 13 P.3d 240, 242-43 (Wash. 2000) (Washington CPA) (citing cases), *review denied*, 29 P.3d 717 (2001); *Fraser Eng'g Co. v. Desmond*, 524 N.E.2d 110, 113 (Mass. Ct. App. 1988) (Massachusetts Act); *Glickman v. Brown*, 486 N.E.2d 737, 741 (Mass. Ct. App. 1985) (same). Thus, the State's knowledge has no bearing where actual deception is not required by the CPA.

### **3. The Government Knowledge Defense does Not Apply to the States' *Parens Patriae* Claims**

For similar reasons, defendants' "government knowledge" defense does not apply to the States' *parens patriae* claims.<sup>17</sup> Defendants fail to explain why the States' *parens patriae* claims are subject to dismissal based on a purported government knowledge defense, where the test is whether defendants' conduct has the capacity or tendency to deceive *consumers*. For instance, defendants provide no hint as to how the "public" – and particularly elderly Medicare Part B co-payors – are supposed to have known that their 20% co-payments are actually inflated as a result of defendants' AWP Inflation Scheme. The States' knowledge simply cannot taint consumers, and defendants present no authority to the contrary.

### **4. Defendants Raise Fact Issues that Cannot be Decided on a Motion to Dismiss**

For numerous reasons, defendants' "government knowledge" defense merely raises fact issues that cannot be considered on a Rule 12(b)(6) motion to dismiss. First, defendants overlook the States' substantial and controlling allegations of fraudulent concealment. *See Nev.*

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<sup>17</sup> Defendants do not dispute the power of the States to bring claims in *parens patriae*, nor could they. *See, e.g., In re Sonsteng*, 573 P.2d 1149, 1153 (Mont. 1977) ("Acting as *parens patriae* the state is vested with both the power and the duty to promote the interests and welfare of its citizens.").



¶¶ 404-12; Mont. ¶¶ 635-43. As the States allege, defendants prevented the States from knowing the actual pricing structures for the drugs and closely guarded their pricing structures and marketing plans from public disclosure. For example, a recent CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug “price discounts are closely guarded as competitive information.” Nev. ¶¶ 404-05; Mont. ¶¶ 635-36. This allegation alone defeats any argument that the States’ were “on notice” of defendants’ frauds, but it is, in any event, a question of fact for later determination.

Whether a party has committed an unfair or deceptive act is also a question of fact. *Brennan v. Carvel Corp.*, 929 F.2d 801, 813 (1st Cir. 1991) (citing *USM Corp. v. Arthur D. Little Sys.*, 28 Mass. App. Ct. 108, 124, 546 N.E.2d 888, 897 (1989)) (decided under “Massachusetts Little FTC Act”). Similarly, “[i]n Nevada, issues of . . . proximate cause are usually factual issues to be determined by the trier of fact.” *Frances v. Plaza Pac. Equities*, 847 P.2d 722, 724 (Nev. 1993). Thus, to the extent that defendants would attempt to turn the “government knowledge” defense into an issue of causation, the issue cannot be determined by the Court at this time.

Likewise, a determination of whether the States were on “inquiry” notice such that they should have, in the exercise of reasonable diligence, discovered the fraud earlier is a fact inquiry to be decided by the fact finder. *See, e.g., Bemis v. Estate of Bemis*, 967 P.2d 437, 440 (Nev. 1998) (the question of when a party should have discovered a cause of action “is a question of fact to be determined by the jury or trial court after a full hearing”) (quoting *Millspaugh v. Millspaugh*, 611 P.2d 201, 203 (Nev. 1980)); *Siragusa v. Brown*, 971 P.2d 801, 812 (Nev. 1998) (“such factual determinations cannot be made as a matter of law”) (applying Nevada RICO); *see also Young v. Lepone*, 305 F.3d 1, 9 (1st Cir. 2002) (“In the archetypical case . . . it is for the factfinder to determine whether a particular collection of data was sufficiently aposematic to place an investor on inquiry notice.”) (Applying federal securities laws).

The handful of federal reports cited by defendants *only engender various fact questions such as whether anyone at the State Medicaid agencies were aware of the reports and, if so, when they became aware of them, to what extent, and what action may have been taken in response thereto*. For instance, discovery into *why* the States reimburse at a specific percentage discount off of AWP will likely have important implications on this issue.<sup>18</sup> In addition, the significance of what the State knew and its responses may also require expert testimony.<sup>19</sup> Furthermore, *not one* of the reports cited by defendants finds or even suggests that defendants had engaged in unlawful activity. And, notably, defendants' argument that governments were aware of their AWP Inflation Schemes conflicts with the fact that the United States Congress was "*shocked*" to learn the nature, scope and depth of the scheme as recently as the Fall of 2000. Nev. ¶ 175; Mont. ¶ 212 (emphasis added). These various fact issues simply cannot be decided on this Rule 12(b)(6) motion and are to be tried later in this litigation.<sup>20</sup>

##### 5. Government Knowledge Cannot, as a Matter of Law, Trump Montana's False Claims Act Count

Even if Montana had known about defendants' AWP Inflation Scheme (and it did not), the False Claims Act focuses on the *defendant's* knowledge of falsehood, not on the

<sup>18</sup> Again, for brand name drugs Montana reimburses at AWP less 15%, while Nevada reimburses at AWP less 10%. Thus, it is hardly "extraordinary" – as defendants claim – that the 1996 OIG sampling in Montana found average discounts of 16.23% off the AWP of brand name drugs when Montana thereafter changed its reimbursement rate for brand names to AWP less 15%. *And it is indeed a far cry from spreads, recently documented by the DOJ, that exceed 1,000% or even 50,000%*. See, e.g., Nev. ¶ 159; Mont. ¶ 196. Thus, the magnitude of specific spreads have important fact and expert-based meanings that cannot be decided at this time.

<sup>19</sup> For instance, in response to the July 11, 1996 OIG report cited by defendants, the Montana Director of Public Health and Human Services explained that (i) any changes to AWP would have to consider dispensing fee issues, and (ii) deep discounts in AWP might encourage AWP inflation. See Defs. Br. at Ex. 8. This hardly constitutes a recognition by Montana that defendants were, at the time, *already* engaged in their AWP Inflation Scheme and were giving out free samples, issuing phony credit memos and the like, to inflate AWP.

<sup>20</sup> Defendants' cases are inapposite. In *Kennedy v. Josephthal & Co.*, 814 F.2d 798 (1st Cir. 1987), the court held that fraudulent concealment was unavailable when the misrepresentations challenged directly contradicted the terms of the offering memorandum explaining that the operation would not be profitable at the prevailing price of coal. *Id.* at 802. As such, plaintiffs were deemed to be "on notice" of the fraud from the moment that the misrepresentations were made. *Id.* at 803 ("For each oral representation that [was] made and upon which appellants claim they relied, there was a direct refutation by the plain language of the offering memorandum."). See also *J. Geils Band Employee Benefit Plan v. Smith Barney Shearson, Inc.*, 76 F.3d 1245, 1256 (1st Cir. 1996) ("The prospectuses fully disclosed the suitability requirements and risk factors and, when read with reasonable diligence, plainly contradict the alleged oral misrepresentations that these were low-risk investments.") (cited by defendants). In stark contrast to these cases in which the plaintiffs possessed the data necessary to evaluate the fraudulent statements at the time the statements were made, here the States never had actual wholesale prices against which the published AWP could be compared.



government's knowledge. *See* MONT. CODE ANN. § 17-8-231(1). It is therefore well settled under the federal analogue that a defendant may be liable under the False Claims Act even if the government knew that the defendant submitted a false claim. The statutory language, legislative history and case law clearly establish that even when the government knows that the claim is false, the defendant may still be liable under the federal Act. *See, e.g., United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995); *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991).<sup>21</sup>

**E. Nevada Has Standing To Assert Its Nevada RICO Claims And Has Properly Alleged The Existence Of The Enterprises**

Claiming that the State is not a "person" under Nevada RICO, defendants contend that Nevada cannot sue for RICO damages. Defs. Br. at 16-17.<sup>22</sup> Defendants are wrong. Nevada RICO does not itself define "person." However, for the purposes of Nevada's criminal laws, which include Nevada RICO, "[p]erson" includes this state or any other state, government or country . . . whenever it is used to designate a party whose property may be the subject of an offense." N.R.S. 193.0205; *see also* N.R.S. 193.010 (providing that this definition of "person" is the governing definition for all of Nevada Revised Statutes Title 15, of which Nevada RICO is a part). Therefore, Nevada is a "person" under Nevada RICO.

Defendants' reliance on the definition of "person" found in N.R.S. 0.039 is misplaced. As defendants themselves admit, that definition applies only when a different statute does not

<sup>21</sup> Government knowledge may be relevant to whether defendant acted "knowingly," but a defendant is entitled to a judgment, as a matter of law, in only very limited *fact-based* circumstances not applicable here. *See, e.g., United States ex rel. Butler v. Hughes Helicopters*, 71 F.3d 321, 327 (9th Cir. 1995) ("if the district court correctly found that the only reasonable conclusion a jury could draw from the evidence was that [the defendant] and [the agency] had so completely cooperated and shared all information during the testing that [the defendant] did not 'knowingly' submit false claims, then we must affirm the directed verdict"); *Hagood*, 929 F.2d at 1421 (same); *Chen-Cheng Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) ("[t]he fact that the government knew of [the defendant's] mistakes and limitations, and that [the defendant] was open with the government about them, suggests that while [the defendant] might have been groping for solutions, it was not cheating the government in [its] effort").

<sup>22</sup> Defendants do not appear to contest (nor could they) Nevada's power to seek Nevada RICO remedies in *parens patriae* on behalf of Nevada consumers.

provide a different meaning. Defs. Br. at 16. But because the Nevada criminal code, of which Nevada RICO is a part, uses a completely different definition, N.R.S. 0.039 does not apply here.

Relying on its motion to dismiss the plaintiffs' federal RICO claims in the private class actions, defendants next claim that Nevada's RICO claim should be dismissed for failure to plead viable RICO enterprises. Def. Br. at 17. Under Nevada RICO, an "enterprise" includes "any union, association or other group of persons associated in fact although not a legal entity." N.R.S. 207.380.<sup>23</sup> Nevada alleges separate association-in-fact enterprises consisting of a single pharmaceutical company and a single publisher, resulting in 39 separate Manufacturer-Publisher Enterprises. Nev. ¶ 453. Thus, the "rimless wheel" that troubled the Court in *AWP*, 263 F. Supp. 2d at 184-85, does not exist here. For this reason, and for the reasons set forth in the private class action Plaintiffs' Memorandum in Opposition to Motion to Dismiss the Amended Consolidated Class Action Complaint at 17-24, which is incorporated herein by this reference, defendants' challenge to the Nevada RICO enterprises must fail.

#### **F. The Complaints Meet The Requirements Of Rule 9(b)**

Defendants argue that the States' Best Price claims and allegations relating to PBMs and other alleged hidden and improper inducements lack the particularity required by Rule 9(b). Defs. Br. at 17-20. Because defendants also raise these arguments in their individual memoranda, the States respond to them in their joint Separate Memorandum in Opposition to Defendant-Specific Memoranda on Motions to Dismiss, which is incorporated herein by this reference. The States also incorporate Section IV.D of the class plaintiffs' opposition memorandum, which outlines how the fraud is carried out in the PBM context.

### **III. CONCLUSION**

For the foregoing reasons, the Court should deny defendants' motion to dismiss.

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<sup>23</sup> Although Nevada courts have apparently not construed this definition, Nevada generally looks to federal RICO law for guidance unless the state statute differs in some material respect from the federal statute. *See Siragusa v. Brown*, 114 Nev. 1384, 1398, 971 P.2d 801 (1998).

By /s/ Signature on file with the Court

DATED: October 10, 2003.

Steve W. Berman  
Sean R. Matt  
HAGENS BERMAN LLP  
1301 Fifth Avenue, Suite 2900  
Seattle, WA 98101  
Telephone: (206) 623-7292  
Facsimile: (206) 623-0594

Thomas M. Sobol  
HAGENS BERMAN LLP  
225 Franklin Street, 26th Floor  
Boston, MA 02110  
Telephone: (617) 482-3700  
Facsimile: (617) 482-3003

COUNSEL FOR PLAINTIFFS  
STATE OF MONTANA AND  
STATE OF NEVADA

Brian Sandoval  
Attorney General of the State of Nevada  
L. Timothy Terry  
Assistant Attorney General  
100 N. Carson Street  
Carson City, Nevada 89701-4714

ADDITIONAL COUNSEL FOR PLAINTIFF  
STATE OF NEVADA

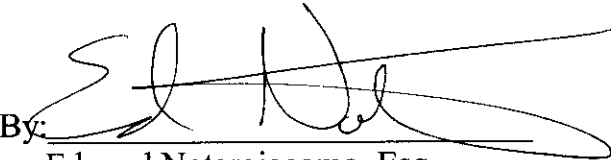
Mike McGrath  
Attorney General of Montana  
Kathy Seeley  
Assistant Attorney General  
Justice Building  
215 North Sanders  
P.O. Box 201401  
Helena, MT 59620-1402  
(406) 444-2026

Joseph P. Mazurek  
CROWLEY, HAUGHEY, HANSON,  
TOOLE & DIETRICH PLLP  
100 North Park Avenue, Suite 300  
P.O. Box 797  
Helena, MT 59601-6263  
(406) 449-4165

ADDITIONAL COUNSEL FOR PLAINTIFF  
STATE OF MONTANA

**CERTIFICATE OF SERVICE**

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copy of the foregoing State of Plaintiffs State of Nevada's and State of Montana's Joint Memorandum in Opposition to Defendants' Motion to Dismiss to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2 on this 10<sup>th</sup> day of October, 2003.

By: 

Edward Notargiacomo, Esq.  
HAGENS BERMAN LLP  
225 Franklin Street, 26<sup>th</sup> floor  
Boston, MA 02110  
(617) 482-3700